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Differentially loaded Radiostereometric Analysis (DLRSA) in Torsion Adds Essential Information in Diaphyseal Bone Healing: the Example of a Tibial Osteotomy

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Abstract

Background Clinical assessment and conventional imaging, which are currently used to monitor fracture healing, do not provide information on the mechanical properties of the healing construct. This limits their use in patient management decisions. Differentially loaded radiostereometric analysis (DLRSA) is a technique developed to assess the mechanical properties of healing fractures *in vivo*. DLRSA measures the relative micromotion of tantalum beads inserted into bone fracture fragments in response to load across the fracture site. To date, these loads have been applied axially, although in fractures fixed with devices which are highly resistant to axial loads, such as locked intramedullary nails, torsional testing may be more sensitive to healing. The aim of this study was to establish a method to investigate DLRSA using torsional loading for clinical application.

Methods A device was designed and built to apply torsional loads to the tibia. The test case was an oblique plain corrective osteotomy of a tibial diaphysis stabilized with an intramedullary nail and with tantalum beads inserted into the two adjacent bone segments. Post surgical examinations were made at 2 weeks, 2, 4, and 6 months as well as 1 and 2 years. Healing was monitored with the use of plain film radiographs, computed tomography (CT) and DLRSA. Axial loads of 30kg and an external torsion of 5Nm were applied during DLRSA examinations and the resultant displacement and stiffness were calculated.

Results Torsional DLRSA demonstrated progressive changes in angular displacements and torsional stiffness consistent with the fracture healing observed by CT. By contrast, axial DLRSA was not informative and was more reflective of the stability of the fixation than healing bone.

Conclusion The addition of torsional assessments to DLRSA provides an important investigative option in assessing the biomechanical properties of bone healing *in vivo*.

Keywords: Tibial Osteotomy; Radiostereometric Analysis; RSA; Differentially Loaded Radiostereometric Analysis; DLRSA; Torsion; Axial compressive load; Bone healing

Introduction

Traditionally, clinical assessment and conventional radiographs have been used to monitor fracture healing. Clinical assessment relies on the reported presence and level of pain during weightbearing and the manual assessment of movement at the fracture site. Conventional radiographs identify the presence of mineralized callus tissue bridging the fracture site [1] and radiological union is usually defined as the presence of three bridging cortices [2]. Although conventional radiographs give an indication of progress toward union, they provide no information about the quality of the healing bone or the mechanical properties of the construct [3-7]. Conventional radiographs are not sufficiently accurate to define an end point to healing of internally fixed fractures and fail to allow early detection of delays or failures of union [6,8-10]. Hence, their utility in supporting important clinical decisions such as optimal and safe loading during rehabilitation, or the timing of fixation removal, is severely limited [11].

Modern computed tomography (CT) has greatly improved our ability to visualize the presence or absence of bridging callus in three dimensions but still does not allow an objective quantitative assessment of mechanical properties of a healing fracture. CT is also associated with significant radiation exposure, limiting its use for serial assessments.

The increasing use of fixation devices in modern practice to provide immediate stability to fractures further masks the clinical state of

healing at the fracture site. There may be little initial pain or movement detected owing to the stability provided by the fixation even though the fracture may remain unhealed. Ultimately, however, the fixation may fail due to metal fatigue if there is insufficient load sharing between the bone and the fixation. This progression from a "load bearing" to a "load sharing" environment occurs as fracture healing progresses and there is increased bridging with new bone across the fracture ends thus reducing the potential for fixation failure.

Fracture stiffness relates to the interfragmentary displacement in response to a given load. Numerous studies have concluded that monitoring stiffness is valuable for assessing fracture healing [11-13]. Some studies report the use of strain gauges on plates and nails to indirectly assess healing from the reduction in load through the

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fixation device [14, 15]. Similarly strain gauges attached to the pins of external fixators are used to indirectly investigate interfragmentary displacements with time and under loading conditions [4,16-20]. Based on these studies, a minimum stiffness value of 15Nm/deg has been proposed to represent clinical fracture healing [21,22]. Although these techniques yield useful information, bone movement is not measured directly and their use is limited to fractures treated with external fixators. A method is required that measures the mechanical properties of healing fractures directly and is not restricted to the use of specific fixation devices.

The radiostereometric analysis (RSA) technique created by Selvik [25] almost 40 years ago is considered the most accurate radiographic method for assessing skeletal micromotion, including movement of prostheses, joint stability and osteotomies [23]. The main use of this radiographic technique has been to make accurate measurements of prosthesis migration, which may be used as a predictor of loosening and early revision surgery. The method requires small tantalum beads to be inserted intraoperatively and two simultaneous radiographs taken over a calibration cage at selected times postoperatively. Using six beads in each segment of proximal tibial fractures, the accuracy and precision have been shown to be less than $0.037\text{mm} \pm 0.016\text{mm}$ for translations and $0.123^\circ \pm 0.024^\circ$ for rotations in all axes [24]. The radiation dose from RSA radiographs is 40% to 50% less than that of standard radiographs, as only the radio-dense tantalum beads need to be identified [25].

In response to a need for objective mechanical assessment of bone healing *in vivo* without the need for external fixation, the technique differentially loaded RSA (DLRSA) was developed in our institution [12]. This is a highly sensitive imaging technique for the accurate *in vivo* measurement of micromotion of bone fragments under load. By combining RSA with an applied load across the fracture site that can be controlled by the patient at the time of examination, a longitudinal measurement of fracture rigidity during healing can be made. To date, loading has only been applied axially in DLRSA, which shows the displacement of bone segments in compression. Although loaded axially, the induced motions may occur (and be measured) in other planes. The initial cases reported [12] had been treated with bridging locking plates, which allowed compressive displacements to occur at the fracture site as the plates bent in response to an axial load. This in turn provided displacements that were sufficiently large to allow meaningful monitoring. Where fracture ends are in direct opposition with intact cortices, however, the potential for direct axial compression is limited. Similarly, fractures fixed with locked intramedullary fixation are very resistant to axial loading, limiting any measurable displacements in this plane. If the screws pass through but are not actually fixed into the nail (usual configuration), a small amount of angular and rotational movement of the nail is possible around the screw. It is therefore reasonable to expect that fracture movements with this type of fixation would be more sensitive to torsional rather than axial loads. Torsion has previously been used to statically assess movements across ankle diastasis injuries [25].

To date, DLRSA has not been used to monitor induced bone displacements in response to applied torsional loads. Hence, the aims of this study were to develop a technique to apply torsional loads using DLRSA and compare torsional loading with axial compressive loading to monitor the progression of healing in a tibial osteotomy treated with a locked intramedullary nail.

Materials and Methods

This study was approved through the Research Ethics Committee

and informed consent was obtained for tantalum bead insertion, DLRSA radiographical assessments and CT imaging.

Torsional Loading Jig Torsional loading was applied using a custom-built jig (Figure 1-Left). The design principle was to stabilize the proximal segment of the fracture by controlling the position of the proximal tibia at the knee joint whilst applying a torsional load to the distal segment with the ankle joint constrained. The jig comprised the lower section of a boot attached to the centre of a rotating disc, through which an external torsional load was applied *via* a weight attached to the outer rim of the rotating disc (Figure 1-Left). The radius of the disc was 0.204 metres and was designed to apply an incremental increase of 5Nm of torque in response to each 2.5kg weight. The foot was held onto the rotating disc using velcro straps (Figure 1-Right). The knee was firmly secured in place in a neutral alignment (patella up), using an adjustable clamp and velcro straps, which confined the knee and restricted its rotation during loading (Figure 1-Right). As the load was applied, the patient was directed to resist any external rotation at the level of the knee and to maintain the original neutral alignment of the knee whilst the DLRSA radiographs were obtained.

Investigative Case A case of a tibial shaft osteotomy stabilized with

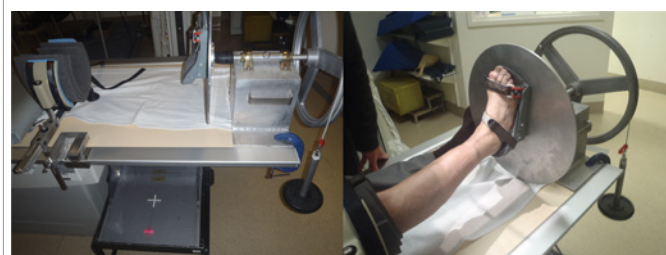


Figure 1: (Left) The torsional loading setup with torsion wheel (far right of picture), knee brace (far left of picture) and RSA calibration cage (below examination table). (Right) The knee and foot were braced firmly with rotation occurring around the centre of the disc at the base of the foot.



Figure 2: (Left) Antero-posterior radiograph of tibial fracture malunion with deformity pre-revision surgery. (Right) Antero-posterior radiograph showing bead placement within diaphyseal segments of the tibia proximal and distal to the osteotomy (circled).



Figure 3: (Left) Torsional DLRSA setup with radiographic tubes angled at 30 degrees from perpendicular to the calibration cage. (Right) Axial loading DLRSA setup with the weightbearing foot positioned on the scales and the RSA calibration cage behind the patient.

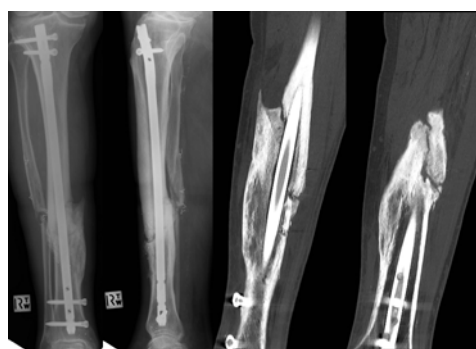


Figure 4: (Far Left) Antero-posterior radiograph and (Left) lateral radiograph of the tibial osteotomy fixed with an intramedullary nail at one year postoperatively. (Right) and (Far Right) Computed tomography (CT) of the tibial osteotomy fixed with intramedullary nail at 1 year postoperatively. Both image slices indicate that union has not been achieved.

a locked intramedullary nail (Trigen®, Smith & Nephew, Tennessee, USA) was chosen to monitor and compare progressive healing using the torsional and axial loading DLRSA techniques. An oblique osteotomy was performed to correct a previous fracture malunion (Figure 2-Left) in an 83 year old man with knee arthrosis, with the goal of restoring normal lower limb mechanical alignment prior to a total knee arthroplasty.

At the time of the osteotomy, tantalum beads (1.0mm diameter, UmRSA, RSA Biomedical, Umeå, Sweden) were inserted into the tibial diaphysis on both sides of the osteotomy using a bead inserter. Seven beads were inserted into both the proximal diaphyseal segment and the distal diaphyseal segment (Figure 2-Right). The beads were positioned in a configuration that allowed sufficient visualisation for optimal RSA [24].

Postoperatively, the patient was assessed at 2 weeks; 2 months; 4 months; 6 months; 1 year and 2 years. These assessments included clinical review, routine antero-posterior and lateral plain film radiographs, torsional and axial DLRSA and CT scanning.

DLRSA setup

Torsional Loading For the torsional DLRSA radiographic assessments, a room-mounted x-ray machine (Philips Bucky Diagnost, Eindhoven, Netherlands) and a mobile radiographic unit (Philips Practix 8000) were positioned for supine x-rays. The RSA calibration

cage was situated below the jig and examination table (Figure 3-Left). The film focus distance (FFD) was 1.6m with x-ray tubes angled 30 degrees to one another. Exposure settings were made at 60kVp and 12mAs, which was sufficient to allow beads to be visualized within the bone. Differentially loaded RSA examinations were taken with the leg in the antero-posterior (AP) position. Pre and post load radiographs were acquired before and after the torsional load was applied.

Axial Loading Axial DLRSA assessments followed the torsional assessments utilizing the same radiographic units repositioned to allow standing X rays as previously described by Chehade [12] (Figure 3-Right). At the initial DLRSA examination, the patient comfortably tolerated 30kg of weightbearing. For the purpose of data analysis the same amount of weightbearing was applied at all subsequent axial DLRSA examinations.

The resultant radiographic images were analysed using the UmRSA software (version 6.0 RSA Biomedical, Umeå, Sweden). Translational and rotational measurements were made in all three planes (x axis, y axis, z axis), corresponding to the orientation of the calibration cage. Each RSA examination was accepted if the condition number, the software generated representation of bead spread, was below 150 [26]. By combining the loading and displacement measurements, stiffness in both torsion (Nm/deg) and compression (N/mm) were calculated.

Results and Discussion

There were no wound complications and weightbearing was commenced “as tolerated” from the time of initial mobilisation. At the six month review, there was still some discomfort reported during ambulation but at the 1 year review there was no longer any pain during weightbearing. Historically, this would normally indicate that there was clinical union.

The plain radiographs taken at each of the assessment times could not be adequately interpreted with respect to fracture healing because of the obliqueness of the osteotomy. This resulted in overlap of the two bone ends, which masked the gap regions. The presence or absence of bridging bone could not, therefore, be determined with any confidence (Figure 4-Far Left and Figure 4-Left).

The CT scans obtained were able to clearly demonstrate the presence or absence of bone bridging the osteotomy gap. No bridging callus was seen across the osteotomy site in any of these investigations taken up to, and including, one year post-operative (Figures 4-Right and Figure 4-Far Right). This finding could be considered contrary to the expectation that some significant union should have occurred by 12 months based on the clinical improvement and painless weightbearing. At 2 years, however, the CT scan demonstrated complete bone bridging of the gap at the osteotomy site, indicating radiological union.

DLRSA examinations using both torsional and axial loading protocols were obtained at all the designated time points. For the torsional loading no difficulties were encountered in the positioning of the patient's leg into the knee clamp or the boot. The application of the 2.5kg weight (5Nm) to the rotating disc did not cause any discomfort and was well tolerated by the patient. The 30kg axial loading protocol was also well tolerated. In the radiographs obtained for both the torsional and axial DLRSA assessments, the beads were all clearly visible. The calculated condition number was less than 150, confirming the adequacy of bead position and spread [26].

The resultant proximal-distal displacement and internal-external rotation of the distal tibia relative to the proximal tibia were recorded under axial and torsional loads (Table 1). The compressive displacements

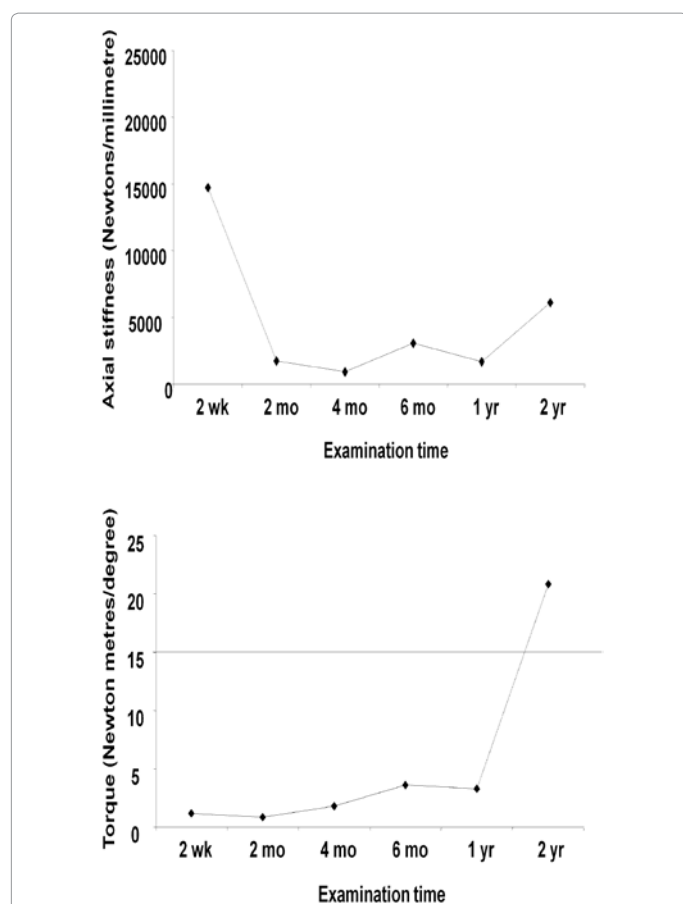


Figure 5: (Top) Axial stiffness of the tibial osteotomy segments during healing. (Bottom) Torsional stiffness of the tibial osteotomy segments during healing with 15Nm/deg representing healed stiffness of bone.

axial rigidity of a locked intramedullary nail [27] (Figure 5-Top). By contrast, the external rotations induced by the torsional loading resulted in angular displacements, which were relatively large (4.23° and 6.02°) in the early stages of healing but decreased progressively to 0.24° at 2 years, when healing was known to be complete based on CT images. Importantly, at the one year assessment, the recorded angular displacement was still relatively high (1.52°), indicating incomplete union, which was consistent with the persistent gap at the osteotomy site demonstrated at the same time on CT (Figure 4-Right and Figure 4-Far Right). The final measurement of 0.24° indicates an *internal* rotation in response to the *external* rotational load. This value may represent a net internal rotatory effect by muscles actively contracting to resist the torsion loading. It is, however, a very small displacement and approaching the accuracy of the technique [24]. A small increase in torsional stiffness was calculated from the torsional DLRSA studies during the first year up to 3.62 Nm/deg (Figure 5-Bottom). At 2 years, when the osteotomy was known to be united, the recorded value was 20Nm/deg. These data are consistent with the findings from studies monitoring angular stiffness with external fixation, where values of greater than 15Nm/deg have been shown to be indicative of bony union [4, 21].

This study demonstrates the value of multiple loading regimens to comprehensively assess fracture healing (both in terms of magnitude and direction). Axial loading has been shown to be very sensitive in monitoring fractures with axial instability, such as comminuted fractures treated with plating or external fixation [12] or tibial plateau fractures treated with screws and plating [28]. In this study, torsional loading has been shown to be sensitive for monitoring bone healing with rigid axial stability and relative torsional instability. Clearly, both techniques are required to assess healing, given the range of fracture and fixation configurations encountered in modern clinical practice. These options can be tailored to exploit the planes least constrained by the fixation.

The data obtained from *in vivo* mechanical assessment of bone healing is critical to the rational, informed decision making regarding patient treatment and rehabilitation. This includes choice of fixation and augmentation; postoperative weightbearing and range of motion protocols; timing of intervention for non progression of union or removal of fixation once union has occurred.

An added potential advantage of torsional testing as described here is that the method can test patients with limited mobility, allowing them to be assessed in the supine rather than the standing position.

A limitation of the design of the jig is that it allows firm but not rigid control and stabilization of the knee and ankle. The resulting transmission of the applied load was likely to be diminished by the effect of compliance by the soft tissues and joint. Another limitation of DLRSA examinations is that muscle contraction can generate forces on the bone segments, resulting in displacement. Despite this, data were demonstrated to be sufficiently sensitive to allow meaningful monitoring and assessments of bone healing in this "fracture-fixation" construct scenario. At this point, we have only demonstrated the feasibility of torsional DLRSA for studies of the tibia, although additional jigs could be designed to accommodate other long bones. The effect of muscle activity may need further consideration when designing test protocols, particularly where the muscle groups are longer and of greater density [29-31].

The study describes a new technique that allows an assessment

Loading	Examination	Load	Rotations (degrees)		Translations (millimetres)	
			Internal rotation +	External rotation -	Proximal +	Distal -
External torsion	2 weeks	5Nm	-4.23		-0.35	
	2 months	5Nm	-6.02		-0.23	
	4 months	5Nm	-2.74		0.21	
	6 months	5Nm	-1.38		-0.46	
	1 year	5Nm	-1.52		0.14	
	2 years	5Nm	0.24		0.17	
Axial compression	2 weeks	30kg	1.01		-0.02	
	2 months	30kg	1.23		0.17	
	4 months	30kg	2.18		0.32	
	6 months	30kg	1.84		-0.10	
	1 year	30kg	0.34		0.18	
	2 years	30kg	0.79		0.05	

Table 1: The resultant proximal-distal displacement and internal-external rotation of the distal tibia relative to the proximal tibia were recorded under axial and torsional loads.

induced by axial loading in this study were relatively small at all time points and did not show any temporal relationship consistent with the progression of healing. The smallest measured displacements of 0.02 and 0.05 mm were recorded at 2 weeks and 2 years, respectively, which is clearly non discriminatory. Although these data did not reflect the clinical course of bone healing, they are consistent with the known

of torsional stability and extends the applicability and versatility of DLRSA in the *in vivo* assessment of fracture repair. Additional data obtained from this technique may better inform our clinical practice, including both surgical and rehabilitation decision making. Further research and development of load application in DLRSA examinations may lead to improvements in accurately identifying bone healing.

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